UNITED STATES PATENT AND TRADEMARK OFFICE

K

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,293	05/07/2001	Robert Falotico	CRD-0931	2210

27777 7590 01/29/2004

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	22

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/850,293	FALOTICO, ROBERT	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment/RCE

This is a response to the Amendment/RCE dated January 8, 2003. Claims 1-14 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. in US Patent No. 6,335,029 in view of Morris et al. in US Patent No. 5,516,781.

Regarding claim 1, Kamath et al. disclose a method for preventing constrictive vascular remodeling via a controlled delivery, by release from a stent (2), as recited in column 3, lines 35-55, of a bioactive compound in therapeutic dosage amounts, as recited in column 5, lines 53-67 and column 6, lines 1-5, in the range from about thirty-five micrograms per fifteen to eighteen millimeters of stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent, as recited in column 5, lines 25-40, where it is assumed that a normal stent has a length of about 14.5cm and a diameter of about 3.5mm, that disclosed is within the range. Further, Kamath et al. disclose the bioactive compound being incorporated in a polymeric matrix having first and second

layers (5 and 20) wherein the compound is substantially in the first layer and the second layer acts as a diffusion barrier for the controlled release of the compound, as recited in columns 5-9, with emphasis on column 2, lines 61-67 and column 3, lines 1-12. Moreover, Kamath et al. also disclose having a thickness in the range from about one micron to about twenty microns, as recited in columns 5, lines 25-40.

However, Kamath et al. do not explicitly recite a bioactive compound having anti-proliferative and anti-inflammatory properties where the compound substantially reducing in-lesion lumen loss both proximate and distal to the stent. On the other hand, Kamath et al. disclose, "The bioactive agents used in the present invention are selected from a number of therapeutic agents depending on the desired application." Further, Kamath et al. disclose the use of both anti-inflammatory agents as well as anti-proliferatives. Moreover, Morris et al. teach to coat a stent with rapamycin, which is known for having anti-proliferative and anti-inflammatory properties. Thus, it would be obvious to one with ordinary skill in the art to use rapamycin as a bioactive compound in the system of Kamath et al., as taught by Morris et al. for its combined properties of an anti-inflammatory as well as an anti-proliferative. Further, a stent coated with rapamycin in the system of Kamath et al. would necessarily yield substantial reducing of in-lesion lumen loss both proximate and distal to the stent, for it is a reaction occurring when a stent such as that of Kamath et al. is coated with rapamycin where the rapamycin eludes from the stent.

Regarding claims 2 and 9, Kamath et al. as modified by Morris et al. disclose that as applied to claims 1 and 8, as well as, when a stent such as that of Kamath et al. is coated with rapamycin would necessarily block a proliferation of fibroblasts in a vascular wall in response to injury, thereby reducing a formation of vascular scar tissue.

Regarding claims 3, 6, 10, and 13, Kamath et al. as modified by Morris et al. disclose that as applied to claims 2, 5, 9, and 12, as well as Morris et al. teach a compound that is rapamycin, as discussed above.

Regarding claims 4, 7, 11, and 14, Kamath et al. as modified by Morris et al. disclose that as applied to claims 2, 5, 9, and 12, as well as, Morris et al. teach a compound that is analogs and congeners that bind a high affinity cytosolic protein, FKBP12, and posses pharmacologic properties equivalent to rapamycin, where the specification of the current application states that rapamycin falls within this limitation.

Regarding claims 5 and 12, Kamath et al. as modified by Morris et al. disclose that as applied to claims 1 and 8, as well as, when a stent such as that of Kamath et al. is coated with rapamycin would necessarily affect a translation of certain proteins in a collagen formation or metabolism.

Regarding claim 8, Kamath et al. disclose a drug delivery device for treating constrictive vascular remodeling having a stent (2); and a therapeutic dosage, in the range from about thirty-five micrograms per fifteen to eighteen millimeters of stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent, of an agent, as recited in column 5, lines 25-40, where it is assumed that a normal stent has a length of about 14.5cm and a diameter of about 3.5mm, that disclosed is within the range. Further, Kamath et al. disclose the agent releasably affixed to the stent, the agent being incorporated in the first layer and the second layers acts as a diffusion barrier for the controlled release of the agent, as recited in columns 5-9, with emphasis on column 2, lines 61-67 and column 3, lines 1-12. Moreover, Kamath et al. also disclose having a thickness in the range from about one micron to about twenty microns, as recited in columns 5, lines 25-40.

However, Kamath et al. do not explicitly recite a bioactive compound having anti-proliferative and anti-inflammatory properties where the compound substantially reducing in-lesion lumen loss both proximate and distal to the stent for treating constrictive vascular remodeling. On the other hand, Kamath et al. disclose, "The bioactive agents used in the present invention are selected from a number of therapeutic agents depending on the desired application." Further, Kamath et al. disclose the use of both anti-inflammatory agents as well as anti-proliferatives. Moreover, Morris et al. teach to coat a stent with rapamycin, which

is known for having anti-proliferative and anti-inflammatory properties. Thus, it would be obvious to one with ordinary skill in the art to use rapamycin as a bioactive compound in the system of Kamath et al., as taught by Morris et al. for its combined properties of an anti-inflammatory as well as an anti-proliferative. Further, a stent coated with rapamycin in the system of Kamath et al. would necessarily yield substantial reducing of in-lesion lumen loss both proximate and distal to the stent, for it is a reaction occurring when a stent such as that of Kamath et al. is coated with rapamycin where the rapamycin eludes from the stent.

3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. in US Patent No. 5,837,313 in view of Morris et al. in US Patent No. 5,516,781.

Regarding claim 1, Ding et al. disclose a method for preventing constrictive vascular remodeling via a controlled delivery, by release from a stent, as recited in column 1, lines 20-30, of a bioactive compound in therapeutic dosage amounts, as recited in column 4, lines 62-67 and column 5, lines 1-8, in the range from about thirty-five micrograms per fifteen to eighteen millimeters of stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent, as recited in column 7, and within the scope of the invention and clearly dependent on the bioactive agent chosen and the number of layer desired. Further, Ding et al. disclose the bioactive compound being incorporated in a

polymeric matrix having first and second layers wherein the compound is substantially in the first layer and the second layer acts as a diffusion barrier for the controlled release of the compound, as recited in columns 5-11, with emphasis on column 5, lines 63-67, column 10, lines 50-67 and column 11, lines 1-5. Moreover, Ding et al. also disclose having a thickness in the range from about one micron to about twenty microns, as recited in column 10, lines 50-67 and column 11, lines 1-5.

However, Ding et al. do not explicitly recite a bioactive compound having anti-proliferative and anti-inflammatory properties where the compound substantially reducing in-lesion lumen loss both proximate and distal to the stent. On the other hand, Ding et al. disclose, to incorporate agents to inhibit hyperplasia and restenosis as well as enhancing the formation of healthy neointimal tissue. Further, Ding et al. disclose the use of both anti-inflammatory agents as well as anti-proliferatives. Moreover, Morris et al. teach to coat a stent with rapamycin, which is known for having anti-proliferative and anti-inflammatory properties. Thus, it would be obvious to one with ordinary skill in the art to use rapamycin as a bioactive compound in the system of Ding et al., as taught by Morris et al. for its combined properties of an anti-inflammatory as well as an anti-proliferative. Further, a stent coated with rapamycin in the system of Ding et al. would necessarily yield substantial reducing of in-lesion lumen loss both proximate and distal to the stent, for it is a reaction occurring when a stent such

as that of Ding et al. is coated with rapamycin where the rapamycin eludes from the stent.

Regarding claims 2 and 9, Ding et al. as modified by Morris et al. disclose that as applied to claims 1 and 8, as well as, when a stent such as that of Ding et al. is coated with rapamycin would necessarily block a proliferation of fibroblasts in a vascular wall in response to injury, thereby reducing a formation of vascular scar tissue.

Regarding claims 3, 6, 10, and 13, Ding et al. as modified by Morris et al. disclose that as applied to claims 2, 5, 9, and 12, as well as Morris et al. teach a compound that is rapamycin, as discussed above.

Regarding claims 4, 7, 11, and 14, Ding et al. as modified by Morris et al. disclose that as applied to claims 2, 5, 9, and 12, as well as, Morris et al. teach a compound that is analogs and congeners that bind a high affinity cytosolic protein, FKBP12, and posses pharmacologic properties equivalent to rapamycin, where the specification of the current application states that rapamycin falls within this limitation.

Regarding claims 5 and 12, Ding et al. as modified by Morris et al. disclose that as applied to claims 1 and 8, as well as, when a stent such as that of Ding et al.

is coated with rapamycin would necessarily affect a translation of certain proteins in a collagen formation or metabolism.

Regarding claim 8, Ding et al. disclose a drug delivery device for treating constrictive vascular remodeling having a stent (2); and a therapeutic dosage, in the range from about thirty-five micrograms per fifteen to eighteen millimeters of stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent, of an agent, as recited in column 5, lines 25-40, where it is assumed that a normal stent has a length of about 14.5cm and a diameter of about 3.5mm, that disclosed is within the range. Further, Ding et al. disclose the agent releasably affixed to the stent, the agent being incorporated in the first layer and the second layers acts as a diffusion barrier for the controlled release of the agent, as recited in columns 5-9, with emphasis on column 2, lines 61-67 and column 3, lines 1-12. Moreover, DIng et al. also disclose having a thickness in the range from about one micron to about twenty microns, as recited in columns 5, lines 25-40.

However, Ding et al. do not explicitly recite a bioactive compound having anti-proliferative and anti-inflammatory properties where the compound substantially reducing in-lesion lumen loss both proximate and distal to the stent for treating constrictive vascular remodeling. On the other hand, Ding et al. disclose, to incorporate agents to inhibit hyperplasia and restenosis as well as enhancing the formation of healthy neointimal tissue. Further, DIng et al. disclose the use of both anti-inflammatory agents as well as anti-proliferatives.

Moreover, Morris et al. teach to coat a stent with rapamycin, which is known for having anti-proliferative and anti-inflammatory properties. Thus, it would be obvious to one with ordinary skill in the art to use rapamycin as a bioactive compound in the system of Ding et al., as taught by Morris et al. for its combined properties of an anti-inflammatory as well as an anti-proliferative. Further, a stent coated with rapamycin in the system of Ding et al. would necessarily yield substantial reducing of in-lesion lumen loss both proximate and distal to the stent, for it is a reaction occurring when a stent such as that of Ding et al. is coated with rapamycin where the rapamycin eludes from the stent.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/850,233. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded

representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/850,507. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 09/850,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of

copending Application No. 09/850,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/575,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,585,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly more narrow in others.

11. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No.

6,585,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a broader recitation of that presently claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700